### 79E-000100US

### **CLAIMS**

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### WHAT IS CLAIMED IS:

- 1. A method of modulating a level of IL-10 in a subject, the method comprising:
  - a) selecting a subject in need of a modulated IL-10 level; and,
  - b) administering an amount of DHEA to the subject, wherein the amount is effective to modulate the level of IL-10 in the subject.
- 2. The method of claim 1, the method further comprising:
  - c) measuring the level of IL-10 in the subject.
- 3. A method of modulating a level of IL-10 in a subject, the method comprising:
  - a) administering an amount of DHEA to the subject, wherein the amount is effective to modulate the level of IL-10 in the subject; and,
  - b) measuring the level of IL-10 in the subject.
- 4. The method of claim 1, 2, or 3, wherein the modulating comprises decreasing the level of IL-10.
- 15 5. The method of claim 4, wherein the level of IL-10 is an elevated level of IL-10.
  - 6. The method of claim 4, wherein the level of IL-10 is a normal level of IL-10.
  - 7. The method of claim 1, 2, or 3, wherein the modulating comprises stabilizing the level of IL-10, wherein the level of IL-10 is an increasing level.
- 8. The method of claim 1, 2, or 3, wherein the modulating comprises decreasing the rate of increase in the level of IL-10, wherein the level of IL-10 is an increasing level.
  - 9. The method of claim 1, 2, or 3, wherein the level of IL-10 comprises a level of IL-10 in a biological sample of the subject.
  - 10. The method of claim 9, wherein the biological sample comprises a biological fluid.
- 11. The method of claim 10, wherein the biological fluid comprises one or more of:
  25 peripheral blood, serum, plasma, urine, vaginal fluid, semen, saliva, peritoneal fluid,
  lymphatic fluid, aqueous or vitreous humor, tears, pulmonary effusion or serosal fluid.
  - 12. The method of claim 9, wherein the biological sample comprises a biological tissue.

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- 13. The method of claim 1, 2, or 3, wherein the level of IL-10 comprises a ratio of IL-10 secreting cells to IFN-y secreting cells in the subject's serum, plasma, or peripheral blood.
- 14. The method of claim 1, 2, or 3, wherein the subject comprises a human subject.
- 15. The method of claim 1, 2, or 3, wherein the subject comprises a nonhuman primate.
- 5 16. The method of claim 1, 2, or 3, wherein the subject has a medical condition, comprising an increased level of IL-10.
  - 17. The method of claim 16, wherein the condition is systemic lupus erythematosus.
  - 18. The method of claim 16, wherein the condition is rheumatoid arthritis, multiple myeloma, lymphoid malignancy, B-cell lymphoma, Sjögren's syndrome, scleroderma, allergic diseases, HIV/AIDS or plasma cell dyscrasia.
  - 19. The method of claim 1, 2, or 3, wherein the subject has a medical condition, which condition can be ameliorated by decreasing the level of IL-10.
  - 20. The method of claim 1, 2, or 3, wherein the administering comprises oral, intracerebral, intrathecal, intraperitoneal, intramuscular, intravenous, subcutaneous,
- transdermal, mucosal or ocular administration.
  - 21. The method of claim 20, wherein the administration comprises administering from about 25 mg/day to about 300 mg/day.
  - 22. The method of claim 21, wherein the administration comprises administering from about 100 mg/day to about 250 mg/day.
- 20 23. The method of claim 22, wherein the oral administration comprises administering from about 150 mg/day to about 200 mg/day.
  - 24. The method of claim 23, wherein the administration comprises administering about 200 mg/day.
- 25. The method of claim 20, wherein transdermal administration comprises25 administration via skin-patch, cream, or topical ointment.
  - 26. The method of claim 1, 2, or 3, wherein administering comprises administration of DHEA and one or more of: a glucocorticoid, a monoclonal antibody specific for IL-10 or a fragment of IL-10, an immunosuppressant, an anti-malarial drug, an alkylating agent, or a chemotherapeutic agent.

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- 27. The method of claim 2 or 3, wherein measuring the level of IL-10 in the subject comprises measuring a basal level of IL-10 in the subject prior to administering the amount of DHEA.
- 28. The method of claim 27, wherein measuring the level of IL-10 in the subject additionally comprises measuring a level of IL-10 in the subject after administering the amount of DHEA.
  - 29. A method of prophylactically or therapeutically treating one or more medical conditions in a subject, the method comprising modulating a level of IL-10 by:
    - a) administering a first amount of DHEA to the subject;
    - b) measuring the level of IL-10 in the subject; and,
      - c) administering at least a second amount of DHEA to the subject, wherein the second amount is determined based upon the level of IL-10 measured in step (b).
- 30. The method of claim 29, wherein the medical condition is SLE, rheumatoid arthritis, multiple myeloma, lymphoid malignancy, B-cell lymphoma, Sjögren's syndrome, scleroderma, allergic diseases, HIV/AIDS or plasma cell dyscrasia.

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